IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES ATTACHED ON EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF NICOLE FLEISCHMANN, M.D.

Plaintiffs hereby seek to exclude certain expert testimony proffered by Defendant Ethicon's ("Defendant") expert Nicole Fleischmann, M.D. ("Dr. Fleischmann"), for all relevant TVT cases in this MDL. Ethicon has submitted Dr. Fleischmann to provide general causation opinions in certain Wave 1 cases[1] and case-specific opinions in certain cases.[2] In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Fleischmann is a Urologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge her qualifications as such.[3] However, Dr. Fleischmann offers opinions in these cases regarding the material properties of mesh, including pore size, weave, density, degradation, and contracture or shrinkage as well as the

[1] *See* Exhibit A for a list of all cases in which Dr. Fleischmann has been identified as a general causation expert.

[2] A separate motion to exclude certain case-specific opinions proffered by Dr. Fleischmann has been filed in *Babcock v. Ethicon, et al.*, Case No. 2:12-cv-01052.

[3] Expert Report of Dr. Fleischmann at p. 1 (attached as Ex. B); *see also* Curriculum Vitae of Dr. Fleischmann (attached as Ex. C.)

TVT's Instructions for Use (IFU), all of which exceed the bounds of her qualifications and are founded on insufficient facts and unreliable methodology.[4]

Dr. Fleischmann's experience in the field of Urology does not render all of her opinions admissible. The admission of Dr. Fleischmann's unfounded opinions would be both contrary to law and presents a serious risk of confusing the issues and misleading the jury in this case.[5] As this Court has recognized in this litigation:

> Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case."[6]

Accordingly, Dr. Fleischmann should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

The Court acts as gatekeeper to determine whether an expert's testimony is reliable and relevant.[7] This gatekeeping function applies not only to "scientific" testimony, but also to testimony based on "technical" and "other specialized" knowledge.[8] The proponent of expert opinion bears the burden of establishing its admissibility.[9] Where the proponent fails to establish all of the prerequisites of admissibility, the exclusion of expert testimony is within the court's

---

[4] *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.)

[5] *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.')(citing *Daubert*, 509 U.S. at 596).

[6] *Cisson v. C.R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 78061, * 42-43 (S.D.W.V. 2013); see also *Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion).

[7] *Daubert*, 509 U.S. at 598 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); Fed. R. Evid. 702.

[8] *Kumho Tire Co., Ltd.*, 526 U.S. *at* 141.

[9] *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

sound discretion.[10] The admissibility of expert opinion testimony is governed by the Federal Rules of Evidence.[11] In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony is a question of and controlled by federal law.[12] In multidistrict litigation, the law of the transferee circuit governs questions of federal law.[13]

The proponent of expert testimony must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible."[14] Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case."[15] An expert's opinion is inadmissible unless the expert is qualified by virtue of knowledge, skill, experience, training or education," which is sufficiently related to the particular subjects at issue in the case.[16] In the context of Rule 702, knowledge "connotes more than subjective belief or unsupported speculation."[17] Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise*."[18] One of the fundamental prerequisites

[10] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997).
[11] *Daubert*, 509 U.S. at 587.
[12] *See, e.g., Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (*quoting Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1054 (4th Cir. 1986)); *Fraley v. Stoddard, D.P.M.*, 73 F. Supp. 2d 642, 646 (S.D. W.Va. 1999).
[13] *See, e.g., In re Temporomandibular Joint Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1155 (8th Cir. 1996) (*citation omitted*), *aff'd*, 490 U.S. 122 (1989)); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) ("[i]n the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law").
[14] *Maryland Cas. Co. v. Therm–O–Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998).
[15] Fed.R.Evid. 702.
[16] Fed. R. Evid. 702; *see, e.g., Cooper v. Lab. Corp. of Am. Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998); *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013).
[17] *Daubert*, 509 U.S. at 590.
[18] *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (emphasis added).

of the admission of an expert's opinion is that it be related to that expert's specialized knowledge.[19]

ARGUMENT

I. THIS COURT SHOULD EXCLUDE DR. FLEISCHMANN'S OPINIONS RELATED TO THE MATERIAL PROPERTIES OF TVT SYNTHETIC MESH

Even though Dr. Fleischmann does not have any experience in material science, has never analyzed, tested, or studied polypropylene mesh, and admits that she is not a materials expert, she arbitrarily offers opinions regarding the material properties of polypropylene used in the TVT.[20] Specifically, she opines that polypropylene does not undergo mechanical changes such as degradation and that degradation if it occurs does not have any clinical significance for patients.[21] Dr. Fleischmann opines that the TVT is composed of macroporous and monofilament "making it an excellent sling material."[22] In her report, Dr. Fleischmann states that the pore size of the TVT is entirely appropriate, but she has never studied pore size and the development of scar plate and bridging fibrosis at a cellular level.[23] Dr. Fleischmann does not have the requisite experience to proffer these opinions, nor has she utilized reliable methodology to reach these conclusions. Dr. Fleischmann's opinions amount to nothing more than assumptions, and the law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent.[24]

---

[19] *See, e.g., U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995).
[20] *See* Ex. B at 31-36; Ex. C.
[21] Ex. B at 33.
[22] Ex. B at 32.
[23] *Id.* at 32; Ex. D at 191:13-18; 192:22-195:11.
[24] *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3 (4th Cir., Sept. 8, 1997)(the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

A. Dr. Fleischman has insufficient knowledge, skill, experience, training and education to opine on topics related to the material properties of polypropylene mesh.

Dr. Fleischmann is a board certified Urologist with a private practice focused on female urology and pelvic floor medicine.[25] Dr. Fleischmann does not have any specialized education or training related to polypropylene or the scientific, chemical or structural make-up of the TVT midurethral sling and/or any of its components including polypropylene mesh.[26] Dr. Fleischmann does not hold herself out as a materials expert or an expert in the material science of mesh.[27] Dr. Fleischmann does not hold herself out as an expert in lightweight or heavyweight mesh.[28] Dr. Fleischmann has not participated in a study involving the histopathological analysis of mesh, including TVT mesh.[29] Because she is not a histopathologist,[30] Dr. Fleischmann defers to pathologists who analyze mesh material under the microscope.

As to her opinions regarding the design of the TVT – i.e., macroporous and monofilament making it "an excellent sling material" and specifically, pore size, Dr. Fleischmann's qualifications as a physician, even a physician specializing in pelvic floor surgery, are not sufficient to allow her to testify on design issues set forth above. In *Tyree v. Boston Scientific Corp.*,[31] this Court excluded opinions by Dr. Jerry G. Blaivas, one of the plaintiff's experts, relating to the design of pelvic mesh products. The Court ruled:

> Dr. Blaivas's experience removing SUI devices and observing complications during the removal process does not alone render him qualified to opine as to design. Dr. Blaivas worked in developing the autologous rectus fascial sling operation. However, this experience in developing procedures does not make him an expert in the design of a medical device. (See Blaivas Report [Docket 239–1],

[25] Ex. B at 1; Ex. C (Curriculum Vitae).
[26] *Id.*
[27] Ex. D at 98:3-12.
[28] Ex. D at 160:6-13.
[29] Ex. D at 98:17-99:2; 194:2-195:22.
[30] Ex. D at 221:7.
[31] 2014 WL 5320566 (S.D.W. Va. 2014).

> at 1–2). As a result, Dr. Blaivas lacks the "knowledge, skill, experience, training, or education" as to product design that Federal Rule of Evidence 702 requires. Fed.R.Evid. 702.[32]

In *Huskey v. Ethicon*,[33] this Court excluded the testimony of Dr. Michael Greenburg, a board certified toxicologist, relating to the biocompatibility and mesh degradation. Dr. Greenberg had never testified about those subjects and admitted he was not a biomaterials expert.[34]

Dr. Fleischmann's qualifications and experience do not rise to the same level as physicians that this Court has found were qualified to testify about design and biocompatibility issues. In *Wise v. C.R. Bard, Inc.*,[35] this Court rejected the plaintiff's challenge to Dr. Marshall Austin, who specialized in gynecologic surgical pathology and cytopathology and examined 15-20 specimens per month, including specimens involving pelvic mesh products. This Court rejected the challenge to his qualifications and ruled:

> In addition to his extensive background in the field of gynecological pathology, where his experience ranges from publishing research to giving academic lectures, Dr. Austin has examined hundreds of vaginal mesh explants over the past ten years. (See generally Austin Report [Docket 203–1]). I find his qualifications sufficient to testify about the biocompatibility of mesh.[36]

Even though the Court determined that Dr. Austin was qualified to testify about biocompatibility, the Court excluded Dr. Austin's opinions on design and concluded:

> I agree with the plaintiffs that these opinions about the Avaulta's overall design go beyond Dr. Austin's expertise. While he has studied and observed the interaction between tissue and mesh products such that he can opine about biocompatibility, he has no demonstrated experience in designing or evaluating transvaginal products.[37]

---

[32] *Tyree*, 2104 WL 5320566 at *47.
[33] 2014 WL 3362264 (S.D.W. Va. 2014).
[34] *Huskey*, 2014 WL 3362264 at *26-27.
[35] 2015 WL. 570070 (S.D.W. Va. 2015).
[36] *Wise*, 2015 WL. 570070 at *3.
[37] *Id.* at *4.

On the other hand, the Court concluded that Dr. Donald R. Ostergard, one of the plaintiff's experts in *Tyree*, was qualified to testify about design issues due to his experience, including experience in the development of pelvic mesh products. The Court ruled:

> After reviewing Dr. Ostergard's curriculum vitae, I conclude that Dr. Ostergard is qualified to provide opinion testimony on the design of polypropylene slings. He has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products.[38]

Dr. Fleischmann has not participated in the design of a midurethral sling. Dr. Fleischmann has not studied pore size or the effect of pore size at the cellular level.[39] She has not participated in clinical trials involving midurethral slings.[40] The basis of Dr. Fleischmann's opinions regarding the design of the TVT is primarily her clinical experience. In light of her admitted lack of education, experience, training and knowledge about the design and suitable properties of polypropylene mesh and specifically how it reacts at the cellular level *in vivo*, Dr. Fleischmann is not qualified and should not be allowed to testify regarding the design of the TVT. These opinions exceed the bounds of her qualifications and should be excluded.

B. Dr. Fleischmann does not use reliable methodology to form her opinions relating to the material properties of polypropylene.

1. Degradation

During her depositions, Dr. Fleischmann was asked questions related to what she did and did not do in order to form her opinions about the mechanical changes of polypropylene mesh, such as degradation. She unequivocally conceded that she has *never* done any of the following:

[38] *Tyree*, 2104 WL 5320566 at *36; *see also Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *7 (S.D.W. Va. 2015) (finding Dr. Ostergard was qualified to testify about design issues).
[39] Ex. D at 194:22-196:22.
[40] Ex. D at 31:19-21.

tested polypropylene mesh[41]; looked at polypropylene under a microscope[42]; or sought out and/or reviewed any additional information from Ethicon regarding whether polypropylene mesh degrades.[43]

The pertinent question to this analysis is not whether or not Dr. Fleischmann is right or wrong. Plaintiffs do not need to challenge these opinions based on their accuracy.[44] The fatal flaw in Dr. Fleischmann's opinions is that they appear to be primarily based on the premise that since she herself has not identified a clinical outcome that in her mind correlates with degradation, then the mesh must not be degrading. Dr. Fleischmann attempts to support her opinions by stating that the evidence of degradation in the literature is "scant."[45] However, Dr. Fleischmann confirms that she reviewed literature and documents provided by Ethicon, but she did not ask Ethicon to provide her with all of the information that they have concerning degradation (only assumed that they would do so).[46] It does not appear that Dr. Fleischmann has performed any specific research or sought out any information directly on this topic. She concedes that she has seen studies that do, in fact, report polypropylene degradation.[47]

Under *Daubert*, a literature review must be performed appropriately in order to be part of a reliable methodology; as part of this, the Court must find more than an expert's own "hypothesis and speculation."[48] Simply because the selective documents provided by Ethicon do not address degradation and she chose to presumptively disregard any literature contrary to

---

[41] Ex. D at 31:19-21.
[42] Ex. D at 98:3-99:2.
[43] Ex. D at 204:14-205:6.
[44] *See Westberry*, 178 F.3d at 261(the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct.)
[45] Ex. D at 204:7-13.
[46] *Id.* at 132:6-11.
[47] *Id.* at 132:6-11; 136:21-138:15
[48] *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 473-74 (M.D.N.C. 2006) (excluding expert testimony based on a literature review, stating that it must be based on more than "hypothesis and speculation," that the review was "disconnected" and not derived by the scientific method.)

her opinion this does not allow Dr. Fleischmann to testify in an expert capacity to an inference that degradation is not possible or if possible, does not have clinical significance. Dr. Fleischmann has admittedly not used any scientific or medical methodology to come to her conclusions, and expert speculation such as this should necessarily be excluded.[49]

2. Shrinkage and Contracture

In her report, Dr. Fleischmann states that medical literature does not provide evidence that the use of the TVT results in excessive contraction of tissues causing complications to patients. Dr. Fleischmann testified that she has not seen a correlation between contracture (along with fibrosis and scarring) and clinical symptoms in her practice.[50] A doctor's personal experience claiming to have not seen evidence of mesh shrinkage or contracture cannot serve as a reliable scientific basis for rendering an expert opinion in Federal court that, *i.e.*, tissue and the mesh within do not contract or "shrink" after implantation.

To the extent that Dr. Fleischmann cites to Dietz H.P., et al., "*Mesh contraction, myth or reality?*," Am J. Obstet Gynecol (2011) 204:173e1-4 in support of her opinion,[51] citation to a single study involving contracture and shrinkage is insufficient to overcome the unreliability problems that plague her opinion in light of her complete failure to consider or account for any contrary scientific authority, and in light of what the article itself states.[52]

> *Daubert* mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the

[49] *Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999) ("A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.")

[50] Ex. D at 192:22-193:21.

[51] Ex. C at 35; a copy of the Dietz article is attached hereto as Ex. E.

[52] Plaintiffs acknowledge that Dr. Fleischmann's mentions Nilsson (2013) in relation to her opinions on contracture, but Nilsson (2013) reports the 17-year clinical data for the TVT and does not involve the measuring of mesh in vivo to study shrinkage and/or contracture. *See* Ex. F.

> "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

In re C.R. Bard, Inc. Pelvic Repair System Prods. Liab. Litig., 948 F.Supp.2d 589, 602 (S.D.W.Va.2013) (*citing Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993)).

The Dietz article points out that mesh shrinkage has been reported in the medical and scientific literature, and discusses that "[s]ome authors have claimed that wide-weave polypropylene mesh may contract 10% per year, reaching a 85% reduction in volume by year 8," citing to an abstract published in the International Urogynecology Journal.[53] The Dietz article acknowledges that "[a]nimal data support the contention that mesh implants shrink in vivo," citing an article in the American Journal of Surgery.[54] The Dietz article also notes that upon ultrasound assessment, "[i]n some cases mesh appears folded and/or contracted after implantation, and in general mesh surfaces seem smaller than prior to surgery." While the Dietz article states that "we found no evidence of mesh shrinkage *beyond 3 months* after implantation," it concedes that "it seems likely that there is some degree of wound contraction within the first few months after mesh implantation, and this is consistent with data in the imaging literature," citing to another article from the International Urogynecology Journal.[55] Thus, far from disproving mesh shrinkage, the Dietz article readily concedes that mesh shrinkage can and does occur and the mechanism by which it can occur, and acknowledges that peer-reviewed, published articles have reported mesh shrinkage.

---

[53] Letouzey V., et al. (2009). "Ultrasound evaluation of polypropylene mesh contraction at long term after vaginal surgery for cystocele repair." Int Urogynecol J 20(Suppl 2): S205-S206 (Ex. G).
[54] Garcia-Urena, et al. (2007). "Differences in polypropylene shrinkage depending on mesh position in an experimental study." Am J Surg 93: 538–542) (Ex. H).
[55] Svabik K, et al. (2009) "Vaginal mesh shrinking – ultrasound assessment and quantification." Int Urogynecol J 20:S166 (Ex. I).

Dr. Fleischmann's opinions purporting to deny that mesh shrinkage has any clinical effect fail under every one of these reliability factors. Such opinions are directly contrary to numerous published, peer-reviewed articles, which establish beyond reasonable scientific dispute the general acceptance of the phenomenon of *in vivo* mesh shrinkage. While Dr. Fleischmann cites one article in support of her "mesh does not seem to contract or shorten" opinion,[56] the article concedes that mesh shrinkage has been observed and reported and that it can and does occur. Moreover, Dr. Fleischmann absolutely fails to mention or account for the numerous peer-reviewed and published articles that establish mesh shrinkage. As this Court recognized in *Tyree v. Boston Scientific Corp.*, Case 2:12-cv-08633, Dkt. No. 444, p. 118 (*Daubert* Order):

> An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*

See also, In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig., 2014 WL 2921648, *9 (E.D.Pa.2014) (expert's "opinion relies upon a selected subset of evidence without sufficient analysis of contrary evidence – a significant methodological weakness…. The fact that her conclusions are drawn from trends she observed in a self-selected subset of supportive studies, not the totality of the epidemiological evidence, further underscores her problematic methodology.").

The overwhelming weight of the published scientific literature establishes mesh shrinkage as a generally accepted scientific phenomenon. Just a few of the many peer-reviewed scientific and medical articles addressing the phenomenon of mesh shrinkage, which Dr. Fleischman completely disregards, are discussed briefly below:

[56] Ex. C at 35.

1. Feiner, B. and C. Maher (2010). "*Vaginal mesh contraction: definition, clinical presentation, and management.*" Obstet Gynecol 115 (2 Pt 1): 325-330. ("Vaginal mesh contraction is a serious complication after prolapse repair with armed polypropylene mesh that is associated with substantial morbidity, frequently requiring surgical intervention.") (Ex. J).

2. Garcia-Urena, et al. (2007). "*Differences in polypropylene shrinkage depending on mesh position in an experimental study.*" The American Journal of Surgery 193: 538–542 ("We conclude that PP meshes undergo an important degree of shrinkage that occurs during the scarring and remodeling process.") (Ex. H).

3. Hansen, N. L., A. Barabasch, et al. (2013). "*First In-Human Magnetic Resonance Visualization of Surgical Mesh Implants for Inguinal Hernia Treatment.*" Invest Radiol. 48 (11): 770-778. ("The amount of tissue reaction [to mesh implants] depends on the inserted material and its pore size. Scar tissue formation can lead to contraction, shrinkage, and deformation of mesh implants. This implant deformation is commonly blamed for severe mesh-related complications such as migration and penetration into abdominal organs, fistula formation, and, most of all, chronic pain, which can occur in up to 30% of cases.") (Ex. K).

4. Klinge, U., B. Klosterhalfen, et al. (1998). "*Shrinking of polypropylene mesh in vivo: an experimental study in dogs.*" Eur J Surg 164(12): 965-969. ("Meshes that contain a lot of polypropylene shrink to about 30%–50% of their original size after 4 weeks, requiring an overlap of at least 3 cm if implanted subfascially. Reduction in the polypropylene content decreases both the inflammatory response and the shrinkage. Meshes with big pores are less likely to fold and improve compatibility." Observing 34% shrinkage of hernia mesh) (Ex. L).

5. Klinge, U., B. Klosterhalfen, et al. (1999). "*Foreign body reaction to meshes used for the repair of abdominal wall hernias.*" Eur J Surg 165(7): 665-673. ("In accordance with the published data,…polyester and polypropylene lead to a pronounced chronic inflammation (2,3, 9) and a strong interlinking formation of connective tissue through the mesh-pores. This embedding connective tissue forms a rigid scar plate and is responsible for mesh shrinkage of 20% in length or 40% in mesh area, respectively, compared with the original mesh in its native, non-implanted condition.") (Ex. M).

6. Klosterhalfen, B., K. Junge, et al. (2005). "*The lightweight and large porous mesh concept for hernia repair.*" Expert Rev Med Devices 2(1): 103-117. ("[T]here is now broad acceptance that shrinkage is a common phenomenon after mesh implantation…. It is not the mesh that shrinks, but the surface reduction is due to a simple retraction of the fibrotic scar tissues around the mesh. Retraction of the scar is a physiologic reaction of maturing scar started by a constant water loss and a subsequent surface-area decrease to an average 60% of the former wound region.") (Ex. N).

7. Letouzey V., et al. (2009). "*Ultrasound evaluation of polypropylene mesh contraction at long term after vaginal surgery for cystocele repair.*" Int Urogynecol J 20(Suppl 2): S205. ("3D Ultrasound reconstruction [showed] a mean contraction of 30%, 65%, 85%, at a mean follow up of 3 years (n=12), 6 years (n=16), 8 years (n=12) respectively. Furthermore, we observed

a linear evolution of the contraction rate between 18 months and 9 years after the mesh implantation.") (Ex. G).

8. Svabik K, et al. (2009) "*Vaginal mesh shrinking – ultrasound assessment and quantification.*" Int Urogynecol J 20:S166 ("We know from experimental studies that the large mesh area caused strong inflammatory reaction which results in integration of the mesh to the tissue and is associated with retraction-shrinkage of the mesh…. The shrinking of the polypropylene mesh is described from 30% to 50% in some animal studies…. The Gynemesh [product involved in the study] shrinks one fifths of its length. The folding has a major impact on the final length of the large meshes (36%) and it seems to be irreversible…. The significant increase in vaginal wall thickness after vaginal surgery is apparently caused by the mesh and not by the surgery.") (Ex. I).

9. Tunn, R., A. Picot, et al. (2007). "*Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele.*" Ultrasound Obstet Gynecol 29(4): 449-452 (observing and reporting significant mesh shrinkage in pelvic organ prolapse mesh with ultrasound) (Ex. O).

Dr. Fleischmann's complete and inexplicable failure to consider or account for any of this abundant literature renders her opinions regarding shrinkage or contracture wholly unreliable. In summary, when giving her conclusions regarding mesh contracture, Dr. Fleischmann disregards the medical and scientific literature and Ethicon's own internal documents and bases her assertion that if there is any contracture or shrinkage of mesh *in vivo* then it is not excessive and has no clinical implications on her belief that she has not seen it in her practice. Dr. Fleischmann's opinion that tissue/mesh shrinkage has no clinical implications should be excluded.

II. THE COURT SHOULD EXCLUDE DR. FLEISCHMANN'S TESTIMONY ON THE TVT'S INSTRUCTIONS FOR USE ("IFU")

In her report, Dr. Fleischmann writes, "The possible risks of TVT are adequately described in the TVT IFU and in Ethicon's professional education materials associated with TVT. The IFU and the professional education materials appropriately take into account the foundational level knowledge of the trained surgeon who is using the product, as is specifically

stated in the TVT IFU."[57] In rendering her opinions regarding the TVT Retropubic IFU, Dr. Fleischmann did not consult published standards governing the information that should be included in a medical device warning.[58] Dr. Fleischmann did not review the testimony of Ethicon witnesses responsible for determining if the IFU's warnings were adequate and if the IFU complied with appropriate standards.[59] Dr. Fleischmann did not review Ethicon documents that address the standards or the criteria that it applied in determining what information should be included in the TVT IFU.[60] Dr. Fleischmann's opinions regarding what she would consider to be an adequate warning are based on her personal experience.[61]

Moreover, while Dr. Fleischmann opines that the IFU adequately describes the known risks of a TVT, she admits that the IFU prior to 2015 does not include warnings regarding known complications of the TVT. Dr. Fleischmann admits that an IFU in place prior to 2015 does not list either dyspareunia or pain as an adverse reaction,[62] but incredibly, she believes that the mention of exposure is a warning for dyspareunia.[63] Dr. Fleischmann admits that frequency, urge and urge incontinence are potential adverse reactions, but these conditions are not included in the adverse reactions section of the IFU.[64]

Dr. Fleischmann is unqualified to testify on the specific issue of product warnings. She is neither familiar with the standards applicable to medical device IFUs nor the process by which IFUs are developed and approved.[65] She does not rely on any standards nor information from Ethicon in rendering her opinions regarding the TVT IFU. Rather, she relies solely on her own

[57] Ex. B at 39 (Expert Report of Nicole Fleischmann, MD).
[58] Ex. D at 27:5-9 (Corbett).
[59] Ex. D at 27:12-19.
[60] Ex. D at 27:20-25.
[61] Ex. D at 28:1-7.
[62] Ex. P at 45:17-23; 49:22-50:2 (Dep. Nicole Fleischmann (Babcock) (March 23, 2016).
[63] Ex. P at 50:18-51:8 (Babcock).
[64] Ex. P at 45:5-11; 45:24-46:3; 46:5-8 (Babcock).
[65] *In re: C. R. Bard, Inc. (Cisson)*, 948 F. Supp. 2d 589, 611 (S.D.W.Va. 2013).

personal opinion and experience. The United States Supreme Court, the Fourth Circuit and this Court have all expressly held that an opinion based on nothing more than the *ipse dixit* of the expert is inadmissible.[66] This Court has previously rejected this "I have not seen any risks in my practice that were not in the defendant's product instructions, so therefore the instructions are adequate":

> Author and astronomer, Carl Sagan, popularized the aphorism, "Absence of evidence is not evidence of absence." Carl Sagan, *The Demon-Haunted World: Science as a Candle in the Dark* 213 (1996). Sagan's aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false. Instead, there is often insufficient investigation and information to come to a conclusive determination. Sagan's musings are relevant here because for the first time during these MDLs, the plaintiffs have challenged the defendant's attempt to offer experts seeking to opine on the adequacy of product warnings. In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks he has observed in his own practice.

Tyree v. Boston Scientific Corp., Case 2:12-cv-08633, Dkt. No. 444, p. 118 (*Daubert* Order). A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and

[66] *See, e.g., General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* [an assertion made but not proved] of the expert"); *Cooper*, 259 F.3d at 202-03 (same); *Bourne v. E.I. Dupont de Nemours & Co., Inc.*, 189 F. Supp. 2d 482, 499 (S.D.W. Va. 2002) (same); *see also Hoffman v. Monsanto Co.,* No. 2:05-CV- 00418, 2007 WL 2984692, *4 (S.D.W. Va. Oct. 11, 2007) (excluding an opinion that was based on "simply a subjective, conclusory approach that cannot reasonably be assessed for reliability") (*quoting* Fed. R. Evid. 702, advisory committee's note (2000)).

not on belief or speculation, and inferences must be derived using scientific or other valid methods."[67] Dr. Fleischmann's opinions concerning the adequacy of the TVT IFU are unreliable and should be excluded.

CONCLUSION

For the reasons above, this Court should grant Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Nicole Fleischmann, M.D.

This 21st day of April, 2016.

By: /s/ P. Leigh O'Dell
ANDY D. BIRCHFIELD, JR.
P. LEIGH O'DELL
WESLEY CHADWICK COOK
Beasley, Allen, Crow, Methvin, Portis & Miles, P.C
218 Commerce Street
Montgomery, Alabama 36104
334-269-2343
andy.birchfield@beasleyallen.com
leigh.odell@beasleyallen.com
chad.cook@beasleyallen.com

/s/Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

[67] *Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir.1999).

CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ P. Leigh O'Dell
Attorney for Plaintiffs